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(71)(72) Applicant and Inventor: SHAW, Thomas, J. [US/US]; 1510 Hillcrest, Little Elm, TX 75068 (US).

(74) Agents: WATSON, Harry, J. et al.; Harris, Tucker & Hardin, P.C., One Galleria Tower, Suite 2100, 13355 Noel Road, Dallas, TX 75240-6604 (US).

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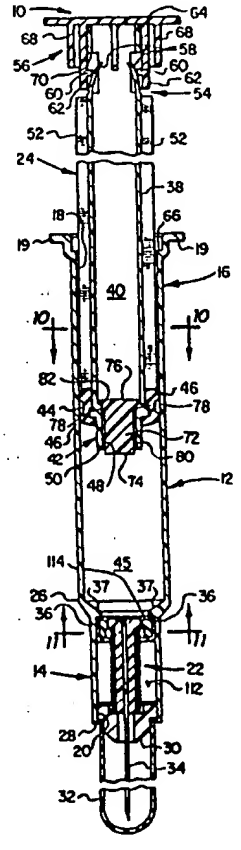
(54) Title: NONREUSABLE MEDICAL DEVICE WITH FRONT RETRACTION

(57) Abstract

A nonreusable medical device has a needle (34) for injecting or collecting fluid which is retractable by depression of a plunger (54) slidingly mounted in the medical device. A front-mounted retraction mechanism (22) has a needle holder connected to the needle. The needle holder is supported along the axis of the device by means of a frictionally engaged retainer ring (102) member coupled to the needle holder along an axially aligned sliding interface. The needle holder and retainer ring are positioned in the front portion of a hollow body. The front of a movable member or plunger presses against the retainer member passing around the needle holder which cannot move forward, thereby separating the retainer member from the needle holder. The separation occurs by gradually reducing the extent of the sliding interface area until the retainer member pops loose from the needle holder whereupon the needle holder and needle are retracted into a cavity in the plunger in response to a retraction force applied to the needle holder by a previously compressed spring.



NONREUSABLE MEDICAL DEVICE WITH FRONT RETRACTION

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a medical device, and more particularly, to a non-reusable syringe having an automatically retracting hypodermic needle which renders the syringe non-reusable after one use.

Background of the Art

Intravenous drug users have been identified as major vectors for the spread of AIDS in the general population because of sharing and reuse of hypodermic needles. With no vaccine in sight and reeducation lengthy and ineffective, a technological solution to discourage needle reuse is imperative. An additional consideration is that IV drug users obtain syringes primarily from the medical industry. Therefore, any device that reaches the drug-using community would also have to achieve acceptance in the health care field. The primary concerns of the health care industry are that new syringes 1) maintain the same capacity to hold fluids and allow for accurate incremental measurement of fluid as compared with standard syringes; 2) permit one-handed use so that the other hand of the health care worker is free to assist in holding the patient; 3) retract fully after use, thereby eliminating the possibility of needle sticks because of a mistaken belief the syringe has retracted fully when, in fact, it has not; 4) can clearly indicate prior use; 5) be extremely reliable even when used at a wide range temperature; 6) be easily assembled for mass production, and 7) be manufactured at an extremely low cost, due to the daily consumption of the product in quantities of millions of individual syringes, while maintaining a zero defect failure rate.

Various syringes with retracting or disarming technology have been devised in an attempt to address the needs of the health care industry. A number of different approaches have been used.

U.S. Pat. No. 4,747,831 to Kulli discloses a syringe-like cannula insertion set with a retraction needle. A manually releasable latch requires two-handed operation to

U.S. Pat. No. 5,084,029 to Tagliaferri, et al., illustrates another approach using a frangible membrane on the plunger and a needle holder which can be hooked by a male hooking pawl which is held in the barrel by small shearing pins. The pins must shear upon application of sufficient force after hooking to allow the needle assembly to be withdrawn from the end of the syringe.

U.S. Pat. No. 5,053,010 to McGary, et al., is another example of a front-mounted retraction device which relies upon molding of structures which break or shear in order to provide a release. The front of the plunger shears through the piston, then breaks off part of the syringe body to release a spring-loaded needle holder. This creates obvious reliability problems in molding a body that will hold the compressed spring, yet break consistently without excessive effort. This device illustrates another potential problem in that failure of the syringe to fully penetrate through the head of the piston, yet breaking the needle-holding parts, could result in driving the needle forward into the patient's body at the moment of intended retraction.

The above-mentioned art illustrates the many attempts to produce a practical automatically retractable non-reusable syringe. The most commonly used syringes are 1cc and 3cc syringes which must be mass-produced at the rate of millions per day. The tiny needles are produced in the form of coiled tubing, and vary significantly from absolute straightness after they are cut to length. This alone leads to difficult assembly problems if the needle must be passed through a small opening. The extremely sharp tip of the needle will catch the edge of a hole and jam the production line. Any hope of high-speed production requires molds with 64 cavities or more to reduce unit cycle time. Therefore, molded structure within the barrel that requiring collapsing core pins such as are shown in some of the art mentioned are unlikely to be producible at competitive costs.

The gravity of the threat posed by AIDS and the fact that the main vector of the spread of the dreaded disease is through reuse of syringes by IV drug users has resulted in intense activity to develop the most practical, most reliable, easily assemblable, mass-producible syringe. A study of the problem reveals at least ten features that a retractable syringe should address in order to be a marketable product in quantities that could impact the spread of AIDS. A failure to address any one of these items could and has prevented the production of a practical retractable syringe. Such a syringe should:

1. Require only one inner contraction in the barrel so as to be formed by the separation of core pins at the kiss off point without the use of collapsible core

technology. If collapsible core technology is required, the product can be rendered noncompetitive due to production costs as a result of excessive cycle time.

2. The device should have a mechanism to prevent accidental retraction when the plunger is pushed all the way forward prior to drawing medications. This helps prevent accidental firing of the retraction mechanism. Syringes that accidentally "fire" and become useless during medical emergencies will never become accepted in the medical community.

3. Once the needle has been retracted, the device should be very difficult or impossible to reuse or reassemble for reuse.

4. The release mechanism should not require bending, flexing, or breaking of any release elements if the force applied by the thumb to initiate retraction is to be constant under various climatic conditions. Designs requiring breakage of parts for release create manufacturing and reliability problems when trying to achieve a very thin breakable membrane.

5. The needle must not advance even slightly forward at the retraction moment, for to do so drives it painfully into the patient.

6. The design must provide for easy assembly methods which do not require guiding the needle into small holes because presently manufactured needles, when epoxied into hubs or needle holders, are not perfectly aligned.

7. The design should not call for the use of minute parts that are delicate and drive up assembly costs while hampering reliability by increasing the risk of hang-ups during retraction.

8. The seals should be sufficient to prevent liquid leakage but must also prevent loss of vacuum. The biasing spring should be effectively sealed from the variable liquid holding chamber.

9. The amount of force required to initiate retraction should be predeterminable and not affected by creep of plastics or require the use of special plastic compositions.

10. The device should not be reusable if the plunger is sufficiently extended during the prior use to cause a retraction.

It would therefore be desirable to produce a practical syringe that meets these requirements. The syringe disclosed herein is the first mass-producible syringe suitable for use in a small size which meets all these requirements.

SUMMARY OF THE INVENTION

A medical device is disclosed having a retraction mechanism equipped with a needle for injecting or collecting fluid which operates on a new principle. The device is primarily useful in the syringe technology where front-mounted retraction mechanisms are employed. It can also be adapted for use as a blood sampling device by providing the usual double-ended needle and replacing the plunger with a collecting tube equipped with a rubber stopper adapted to operate the retraction mechanism.

The retraction mechanism comprises a needle holding member which is surrounded by a retainer member, the needle holding member and retainer member being separable members coupled, along a sliding interface oriented in the direction of retraction, with a friction force which exceeds the retraction force. The direction of retraction is substantially parallel to the longitudinal axis of the device, such as a syringe, or only slightly angled from the axis to facilitate reproducible and reliable assembly of the retainer member to the needle holding member.

The needle holding member and retainer coupled at the sliding interface, are mounted in the front end portion of an elongate hollow body containing a movable member such as a syringe plunger. The needle holding member, together with a hollow needle fixed therethrough, are mounted in the center of the hollow end portion with the needle extending along the central axis of the device. The needle holder, but not the retainer member, is restrained from forward movement by a closure member mounted at the front tip of the hollow front portion. The closure member does not also restrain the retraction member.

Retraction is initiated by relative movement between the needle holding member and the retainer member caused by selective movement of the movable member toward the front of the device. Retraction occurs by reduction of the extent of the sliding interface in response to movement of the movable member, until the retraction force exceeds the friction force, whereby the needle holding member separates from the release element by moving forward, allowing the needle holder and needle to move into the retracted position under the influence of the biasing element.

More particularly, an elongate hollow body has a hollow first end portion separated by a transition zone from a second hollow end portion. Substantially all of the retraction mechanism is located within the first end portion of the body below the transition zone. The transition zone includes a stop member against which the retainer member is positioned prior to retraction. The retainer member is smaller in height than the needle holding member such that the retainer member is free to move axially when urged to move

The wall of the head portion of the plunger extends forwardly ahead of the piston and contains a dislodgable plug member which seals the entrance to the retraction cavity in the movable member or plunger. The dislodgable member is dislodged, upon movement of the movable member from the first position to the second position, by contact with the needle holding member, preferably before the needle holding member is separated from the retainer member during selective movement of the movable member to effect retraction.

Thus it can be seen that the invention embodied in a syringe in the usual tubular cylindrical construction can be filled with an injection fluid in the usual manner and adjusted to remove the air bubbles and adjust the dose. When the plunger is moved forwardly, the variable fluid chamber is reduced in size and fluid is ejected through the hollow needle fixed in the center of the needle holding member. At the end of the injection stroke, the front wall or lip of the head of the plunger is positioned immediately in the presence of the retainer member in line with the retainer member without also being positioned in line with the needle holding member. This is the first position of the plunger. Further depression of the plunger in the forward direction causes the front part of the plunger to begin pressing on the retainer member and dislodging the plug member. Continued depression of the plunger begins moving the retainer member in a forward direction away from the stop members reducing the extent of the sliding interface area. The needle holder remains in its original position because it is bottomed out against the tip closure. The plug member is slidingly dislodged during gradual reduction of the sliding interface.

As the plunger continues to move forwardly from the first position toward the second position, the retainer member (ring) is shifted axially and the sliding interface is gradually reduced until finally the frictional engagement between the retainer member and the needle holder is less than the retraction force provided by the spring, the retainer separates from the head of the needle holder and the spring drives the needle holder and needle along with the dislodgable plug member into the retraction cavity in the center of the plunger thereby effectively and permanently retracting the needle inside the hollow body. The front portion at the head of the plunger may also be equipped with hooked portions which pass through the internal opening in one direction during movement of the plunger in order to effect separation of the retainer member from the needle holder. The hooked portions engage locking means which are preferably a portion of the stop members themselves, such that the interengagement of the hooked portions with one or more locking surfaces prevents movement of the plunger in the retraction direction after retraction has occurred.

retraction cavity, but neither of these structures require collapsible core pin technology which can greatly extend cycle time in mass production. Core pins can be put in from both directions to form a first reduced diameter front portion.

The dislodgable plug member is easily installed through the open rear end of the plunger and pushed forward until a land engages a reduced diameter of the front opening or entrance portion of the head of the plunger to hold the plug member in sealing contact with the inner surfaces. The cap member is then installed at the rear to close the opening after the plug member is inserted.

The retainer member preferably has sufficient depth to provide a stabilizing. positioning and locating function with respect to the needle holder by contact with the walls of the open front end portion of the body. The combined needle holder and retainer member are slid in sealing contact with the side walls up to the transition zone, the spring inserted over the stem of the needle holder and the closure member cap fixed in place by compressing the spring. The spring is isolated from any fluid introduced into the fluid chamber above the transition zone. Assembly can be accomplished by automated mechanized means. No tip seal is required which permits a large opening which easily accommodates slight misalignment with the needle off the true central axis of the device.

The many advantages of the invention will be seen in the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a longitudinal cross-sectional view of a first embodiment of the invention illustrating a syringe in shipping position with the plunger partially withdrawn;

Figure 2 is the embodiment of Figure 1 with the plunger in the depressed position at the end of the injection cycle;

Figure 3 shows the plunger end cap after movement from a first position to a second position in preparation for automatic retraction of the needle upon further forward movement of the plunger;

Figure 4 shows embodiment of Figures 1-3 with the needle assembly retracted into the hollow interior of the plunger in response to movement of the plunger from the position of Figure 3 to the position of Figure 4;

Figure 5 shows an enlarged embodiment of Figures 1-4 as the front of the plunger comes into contact with the needle assembly to begin the retraction stroke;

12. The first end portion or head 42 terminates at a lip 50 defining an opening 48. The syringe body 12, plunger assembly 24 and the openings therein are preferably circular, as shown, like a standard syringe. Plunger wall 38 preferably has radially extending projections 52 best seen in Figure 10. These projections extend longitudinally upwardly from the first end portion or head 42, terminating a short distance from the back end. Projections 52 serve as sliding guide members for the plunger to maintain its lateral position on the central axis of syringe body 12. At the back of the plunger, second end portion 54 is formed to include a positioning means for a two-position end cap 56 which fits over the back end of the plunger. Two to four flexible fingers 58 molded into wall 38 are surrounded by an open slot in wall 38. Fingers 58 are forced inwardly by complimentary radially inwardly extending projections 60 formed in a downwardly extending wall element 62 depending from a horizontal thumb bar 64 of end cap 56. Wall element 62 may be an annular wall with projections 60 located to cooperate with flexible fingers 58. To complete the structure, another circular wall 68 depends from thumb bar 64 of cap member 56 spaced outwardly from wall 62. An annular abutment ledge 66 formed on wall 38 serves as a stop for the end of wall 68.

The general idea of movable end cap 56 is that it provides a means for positioning plunge assembly 24 in two positions within the syringe body. When end cap 56 is in a first position represented in Figure 1, plunger travel is limited because wall 68 bottoms out by contact with ledge 66 formed in the upper end of the syringe body. When end cap 56 is moved back to a second position represented in Figure 3, plunger head 42 can move closer to the front of the syringe sufficiently to trip a retraction mechanism before end cap 56 bottoms out. The first and second positions of the end cap correspond to first and second positions of the plunger.

Annular wall 68 is preferably opaque to surround and hide a colored surface at the uppermost end of second end portion 54 in the first position shown in Figure 1. A brightly covered area covered by opaque member 68 is exposed when the end cap is moved axially rearwardly to the second position with respect to end portion 54 of the plunger. When end cap 56 is pulled back with respect to the remainder of the plunger from the first position to the second position, the projections 60 lock in gaps 70 above fingers 58. In Figure 3, fingers 58 flex outwardly to rest under projections 60 and prevent the end cap from being moved relative to the plunger. The end cap is in effect locked into the second position and cannot be returned to the first position. A longitudinally extending guide 57 and

part of cavity 112 in lower end portion 14. Consequently, no seal is needed at the tip of the syringe where the injection needle exits.

Assembly is exceedingly easy because needle 34 can be epoxied or otherwise fixed in needle holder 84 as indicated in Figure 5, retainer member 102 can be frictionally engaged with head 88, spring 96 is slid over stem 86 and the whole needle assembly pushed upwardly positioned against stop 36. The closure member then holds the whole needle assembly in position. No seal is necessary at the lower end of front end portion 14.

Returning to Figure 2, one sees plunger 24 in the first position with the end cap also in the first position. Needle 34 may be passed through a membrane into a body of injection fluid which is drawn into variable chamber 45 by pulling back on end cap 56. This preferably moves the end cap to the second position illustrated in Figure 3. After the syringe has been filled with sufficient fluid and adjusted to remove air and excess fluid, it is ready for the injection and retraction cycle. With the injection needle in place, the plunger is depressed. All but a tiny amount of the fluid flows from chamber 45 through needle 34. At the end of the injection stroke and beginning of the retraction stroke, the piston is in the position shown in Figure 2, except that the end cap is in the second position of Figure 3. Now the plunger can be depressed still further beyond the first position.

As the plunger moves forward, lower end 74 of plug member 72 is in contact with the upper end surface of head 88 of the needle holder. Since the lower end 90 of needle holder 84 is bottomed against closure member 30, the needle holder can't move. Forward movement of plunger 24 dislodges plug member 72 by moving land 78 relative to sealing surface 82. This causes plug member 72 to begin moving backward within cavity 40 toward end cap 56. Simultaneously, lip or end 50 of the plunger comes in contact with transverse upper surface 114 of retainer 102. Further depression of plunger 24 causes retainer 102 to begin separating from the head of needle holder 84 by sliding axially along sliding interface 104. Lip 50 pushing against transverse surface 114 slides the retainer relative to the needle holder until the needle holder is separated from the retainer member whereby the needle holder and needle are driven into the hollow interior of the plunger under the influence of compression spring 96 driving needle holder 84. Plug member 72 is carried along into space 40.

Figure 4 illustrates the retracted position of the needle holder and needle after the needle holder has moved in response to the retraction operation just discussed. It shows the position of the retainer member just after axial movement of retainer member 102 in response to depression of the plunger releases the needle holder by gradual reduction of the

slidable sealing surface in contact with syringe body wall 106a, either directly or through a sealing member 108a in contact with the outer surface 116a of retainer 102a. Retainer 102a either directly or indirectly, through the interposition of sealing member 108a, is held against a lower surface 120 of inwardly projecting stops 36a. Retainer 102a may have an upper portion 118 extending past stops 36a into the bottom of variable chamber 45. Stops 36a project radially inwardly and have the locking surface 120 against which the retainer member is held under the biasing influence of the spring acting on the central needle-holding part 84a.

Plunger assembly 24a in Figures 6-9 has a wall 38a defining a hollow interior 40a, first end portion 42a, which may be referred to as the head of the plunger, and an opposite second end portion 54a. Head 42a carries a piston 44a in sliding sealed contact with the wall of the hollow interior of body 12a. The head of the plunger has a reduced diameter which forms a hollow 48a with a sealing surface 82a at the upper end comprising a means for sliding sealing engagement with a land 78a formed under the head 76a of a dislodgable plug member 72a. This is like plug member 72 of the first embodiment, except having a longer body 80a and a suitable diameter to permit dislodgably sealing the head so that fluid does not enter cavity 40a.

In the case of plunger assembly 24a, head 42a has a plurality of angularly shaped hooked projections 122a also seen in Figure 12. These are extensions beyond lower face 74a of dislodgable plug member 72a. Projections 122a are straight (arcuate) extensions of the wall of head 42a with an outwardly extending hook or barb which is designed to catch locking surface 120 under inwardly facing stops 36a when the plunger is depressed for retraction. The hooks prevent subsequent withdrawal of the plunger. Since the plunger in the second embodiment is much closer to the inside diameter of the syringe body, no guide members are needed along wall 38a. Plunger assembly 24a still includes a two-position cap member 56a which is indicated schematically in Figures 6-8 as a circular cap with flat bottomed angled grooves which selectively engage corresponding teeth on the outside of the upper end of the plunger. It could be the two-position cap member 56 or some other cap that selectively moves between the first and second positions to so position the plunger.

The operation of the second embodiment is best illustrated by reference to Figure 6-8 and 9. In Figure 6, the plunger is illustrated just at the end of the injection cycle. The distal ends of hooked projections 122a are aligned with and about to come into contact with the upper surface of retainer member 102a. The inside diameter between hooked projections 122a is such that the opening created therein cannot also come in contact with any portion of the head 88a of needle holder 84a. The plunger now moves axially in response

The head of the needle holder and the inside diameter of the retainer member are frictionally engaged and slid into the open end of front portion 14a. By contact with the inner wall of the cavity 112, the retainer member self-aligns the needle holder and needle on the central axis of the syringe. Self-alignment is provided by depending portions of the retainer which extend below the head of the needle holder. They are not essential. The spring is then placed on the stem portion of the needle holder and the tip closure goes on last. The needle is accessible from the side to hold the needle while the closure tip is put on.

The plunger member may be assembled as a unit and then simply inserted into the opening 18,18a. Plug member 72,72a is inserted through the opening in the back of the plunger and is easily sealingly engaged in position by application of a force from that direction. Then cap member 56,56a is installed to close the back end of the plunger and provide for the two-position operation. It may be necessary to provide a means for spreading the downwardly depending portions of the cap member in order to get it started on the end of the plunger. Longitudinal separations in the wall may be provided for that purpose. Both embodiments are assembled in the same general way.

In the best mode, the parts are circularly shaped as indicated in the cross-sections, although the invention contemplates any polygonal cross-section could be used. The parts are preferably injection-molded from suitable plastic, except for piston 44,44a, seal member 108,108a and the metal spring. The piston is suitably a rubber compound. The plug member is preferably plastic, also, but could be molded from a suitable rubber compound, as well.

The invention is well-suited for production in a 3cc delivery size with the diameter and length selected to provide the appropriate interval spacing for marks on the body to determine dosages. No seal is required at the front of the syringe. The front tip is preferably sonically welded to prevent disassembly for reuse. The tip can also be flat instead of conical.

The syringe does not require a different barrel length to accommodate needles of different length. The length of the needle holder and spring are selected to retract a sufficient distance to accommodate the longest needle. The design is such that any shorter desired needle length will be retracted, as well.

The retainer member or ring could be a hard rubber or a tight-fitting plastic, but is preferably the same material as the needle holder. If used without the seal member, the retainer ring is larger so that it seals against the inner walls of chamber 112. Use of the

slightly less into the variable chamber. Adjustable positioning of the closure member assures that the needle holder is securely held. This arrangement makes possible a wide range of initiating retraction force to suit any desired operating condition.

It is also contemplated that the plunger could have a single position end cap instead of a two position end cap. The pressure required to complete the injection cycle by force applied to depress the plunger is not normally very great. If it requires, for example, a force of one or two pounds on the plunger to cause retraction, it is relatively easy for the user to determine when the front end of the plunger hits the retainer member to complete delivery of the dose. Then a substantially greater force on the plunger will cause the retraction that effectively and permanently prevents reuse. Inspection of the syringe through the clear walls of the device clearly shows the dislodged plug member and needle holder in the plunger which signifies the fact that retraction has been implemented.

by retraction force from the biasing element applied to the needle holding member, said release element comprising a retainer member surrounding a portion of said needle holding member.

4. The medical device of claim 3 characterized in that the combined needle holding member and retainer member slidingly seal said first end portion from said second end portion below said transition zone, in a manner that prevents fluid introduced above the transition zone from contacting the biasing element.

5. The medical device of claim 4 characterized in that the needle holding member has a head portion and a stem portion, said stem portion serving as a guide for a biasing element which comprises a spring, said head portion having a laterally facing surface which frictionally engages the coupled retainer member and defines said sliding interface.

6. The medical device of claim 5 characterized in that the stem portion of the needle holding member is supported by a tip closure member through which said needle member is extended and retracted.

7. The medical device of claim 3 characterized in that said elongate hollow body is defined by a longitudinally extending wall which at the transition zone is inwardly laterally constricted by the presence of said stop member to define an internal opening into the hollow first end portion of the elongate hollow body, said release element is a retainer member surrounding and centrally positioning said needle holding member and said movable member has a head portion at the front thereof capable of passing through said internal opening in order to push against said retainer member without also pushing against said needle holding member to effect retraction.

8. The medical device of claim 7 characterized in that said retainer member is larger than said internal opening and said needle holding member is smaller than said internal opening such that a portion of said retainer member extends laterally inwardly,

that correspond with the first and second positions of the movable member, which cooperates with the elongate hollow body to selectively position the movable member in said positions.

14. The medical device of claim 1 characterized in that said movable member has a front portion and a rear portion, the movable member being selectively movable to position the front portion in line with said release element without also being positioned in line with said needle holding member in order to effect reduction of the extent of said sliding interface upon further movement of the release element without further movement of the needle holding member.

15. The medical device of claim 14 characterized in that the movable member has a means for selective positioning the movable member in a first position and a second position, said first position placing the front portion of the movable member in the immediate presence of said release element where it is capable of initiating said relative movement of said release element upon further movement, said second position being a sufficient distance beyond said first position to cause sliding separation of said release element from said needle holding member to allow retraction to take place.

16. The medical device of claim 15 characterized in that the means for selective positioning of the movable member is a two position cap member mounted at said rear portion of the movable member.

17. The medical device of claim 16 characterized in that the two position cap member has a first position corresponding to the first position of the movable member and a second position corresponding to the second position of the movable member,

the cap member being equipped with limiting means for stopping forward movement of the movable member beyond the first position when the cap member is in the first position.

whereby said plug member is dislodged by sliding of the plug member at said land in response to contact between the body of the plug member and the needle holding member during said movement of the movable member.

25. The nonreusable syringe of claim 24 characterized in that said transition zone includes a stop member against which the retainer member is positioned, prior to retraction, said retainer member surrounding a portion of said needle holder by means of frictional engagement at said sliding interface which exceeds a retraction force applied to the needle holder by the biasing element.

26. The nonreusable syringe of claim 25 characterized in that the head portion of the plunger having a lip defining an entrance to a retraction cavity within, said plunger being selectively movable to position said lip in line with the retainer member without also being positioned in line with the needle holding member in order to effect reduction of the extent of said sliding interface upon further movement of the retainer member without further movement of the needle holder.

27. The nonreusable syringe of claim 26 characterized in that the plug member slidingly seals the entrance to the retraction cavity, the plug member being slidingly dislodged therefrom during gradual reduction of the sliding interface between the needle holder and retainer member caused by axial movement of the retainer member in response to depression of the plunger.

28. The nonreusable syringe of claim 26 characterized in that the transition zone is inwardly laterally constricted by the presence of said stop member to define an internal opening into the front portion of the hollow syringe body;

said lip at the front of the head of the plunger being capable of passing through said internal opening in order to push against said retainer member without also pushing against said needle holder to effect retraction.

29. The nonreusable syringe of claim 28 characterized in that said plug member is slidingly dislodged by contact with the needle holder caused by depression of the

31. In a nonreusable syringe for dispensing fluid medication, comprising a syringe body having a hollow interior and opposite open front and back ends, a needle mounted extending from a front end of the body and communicating with a variable fluid chamber defined by a plunger extending from an open back end of the syringe body and having a head sliding in sealed contact with the interior of the syringe body, the plunger movement serving to fill the variable fluid chamber of the hollow syringe body by drawing fluid from a source through the needle and to deliver fluid out of the needle after filling, where movement of the plunger at the end of the delivery movement toward the front end of the syringe body thereby triggers a retraction mechanism to retract the needle within the syringe body, the improvement comprising:

mounting the needle in a separable two part needle assembly at the front of the syringe body, one part being a central needle holding part biased inwardly by a spring mounted forwardly of a portion of the central needle holding part, the other part being a separable frictionally held retainer surrounding and frictionally engaging a portion of the first part, said retainer extending laterally and having a slidable sealing surface in contact with the syringe body and being held against a stop positioned around the hollow interior of the syringe body which does not also contact said one part;

the plunger having a hollow interior and a lip on the plunger head which is positioned to encounter said retainer at the end of the delivery stroke without also encountering said one part; and

wherein movement of the plunger slides the retainer part with respect to the central needle holding part thereby reducing the frictional engagement between said two parts until the biasing force applied to the central needle holding part exceeds the frictional holding force to cause separation of said separable parts whereby the needle is permanently retracted into the hollow plunger.

are driven into the hollow interior of the plunger away from the open first end of the syringe body, which cannot thereafter be reused.

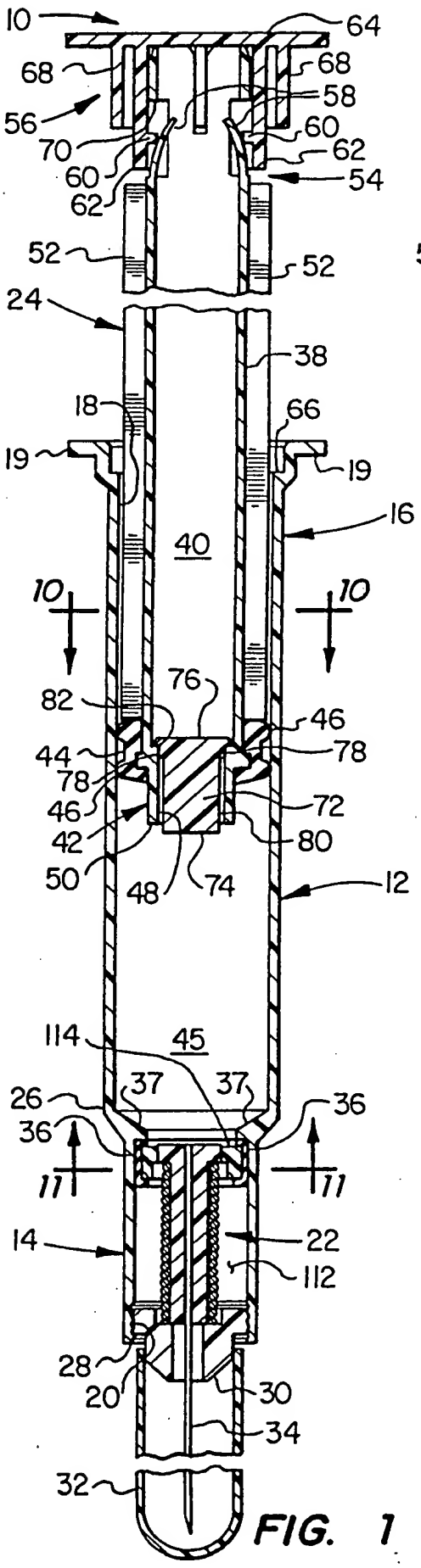


FIG. 1

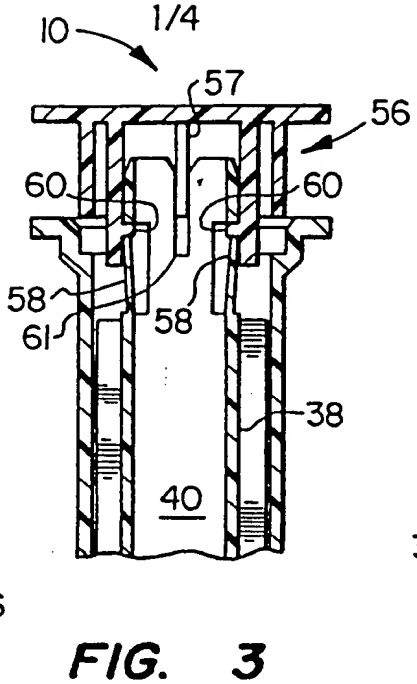


FIG. 3

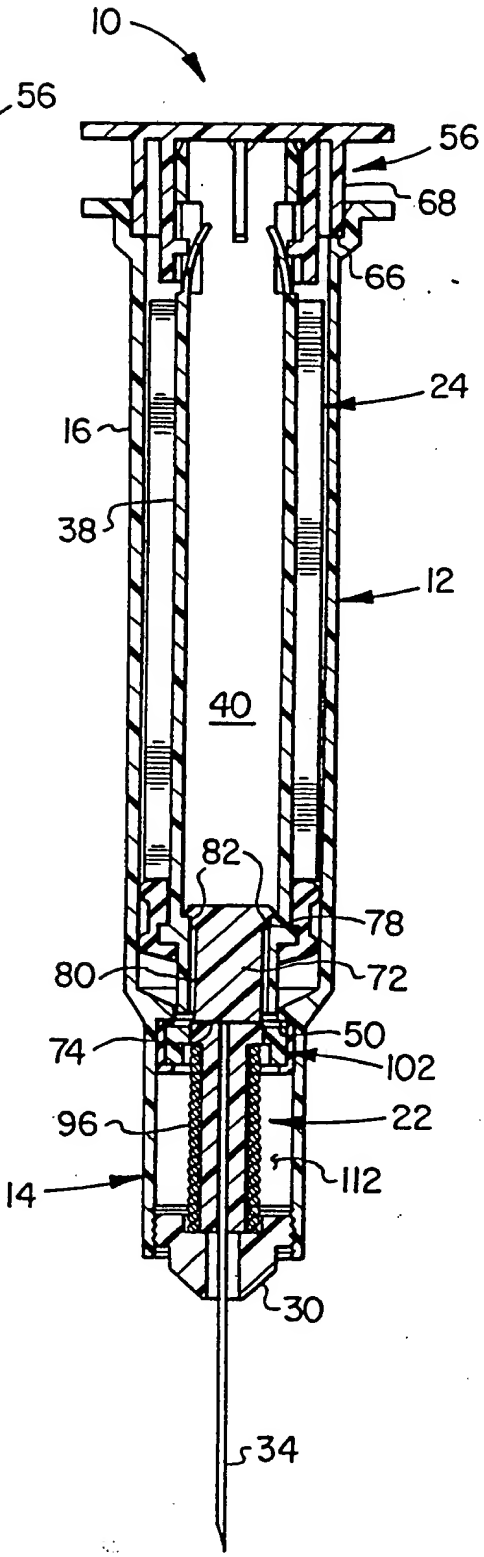


FIG. 2

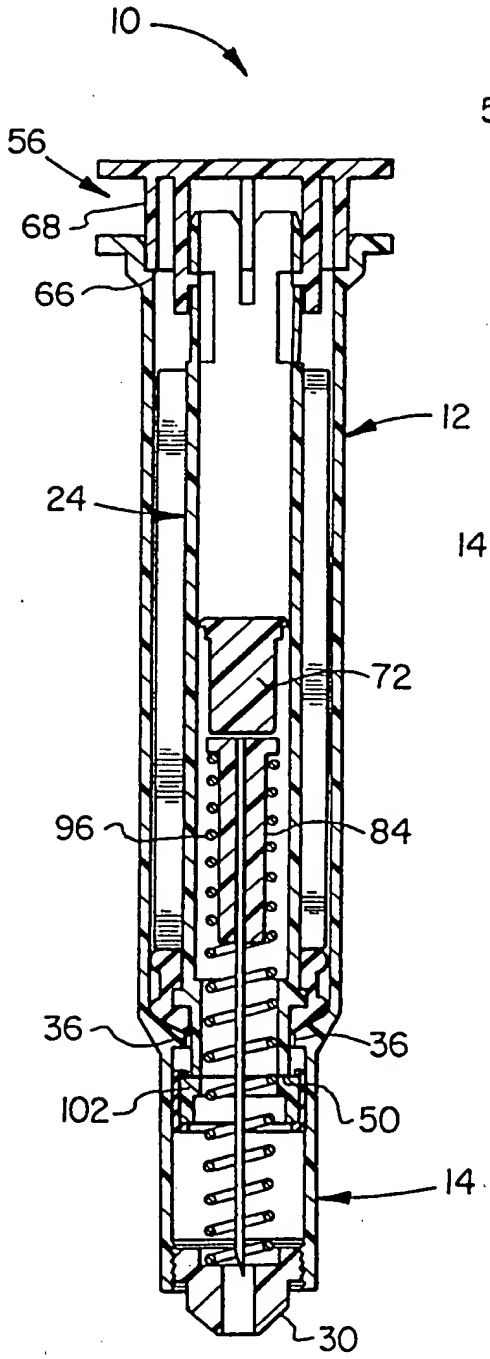

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FIG. 4

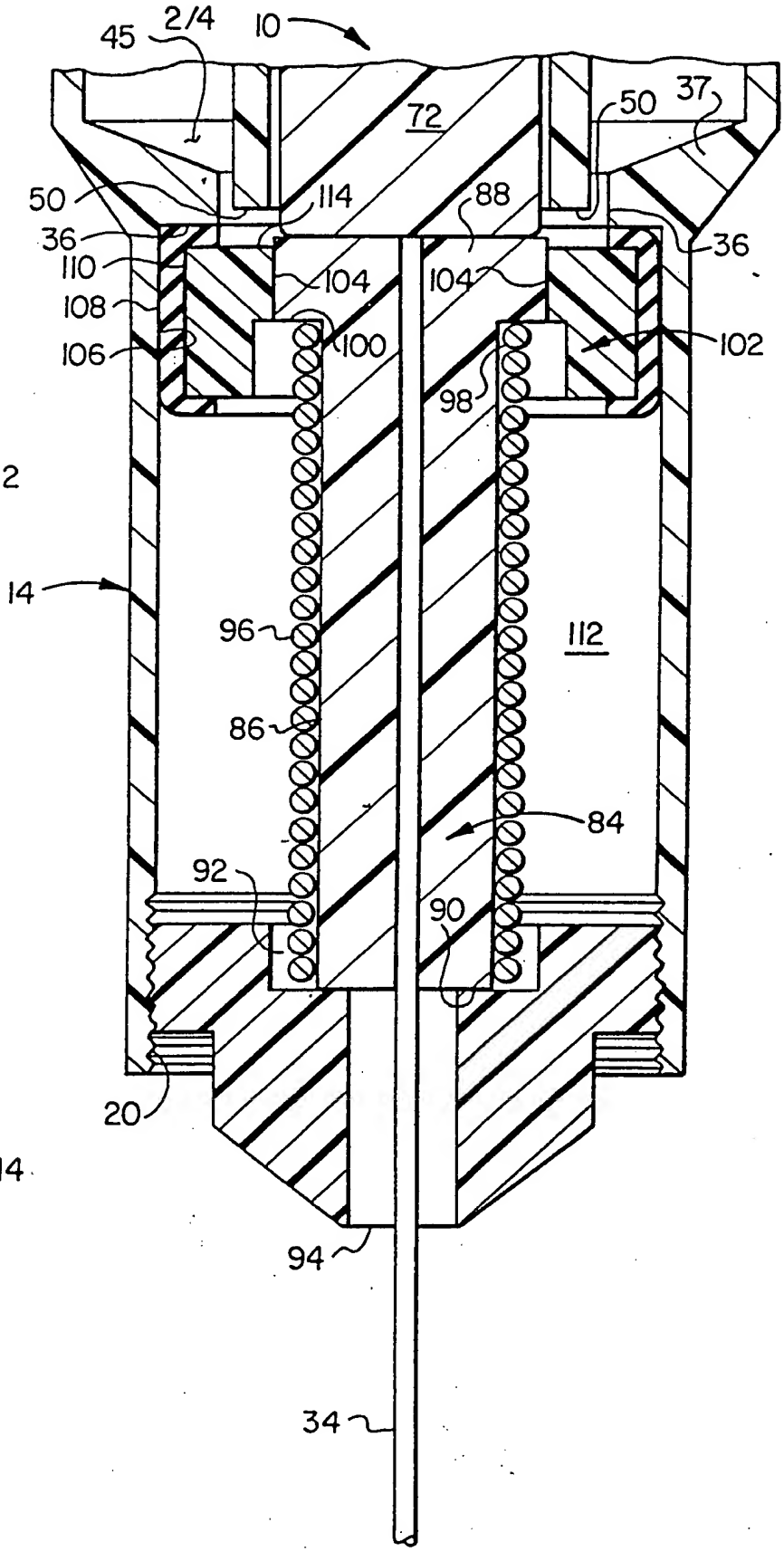
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FIG. 5

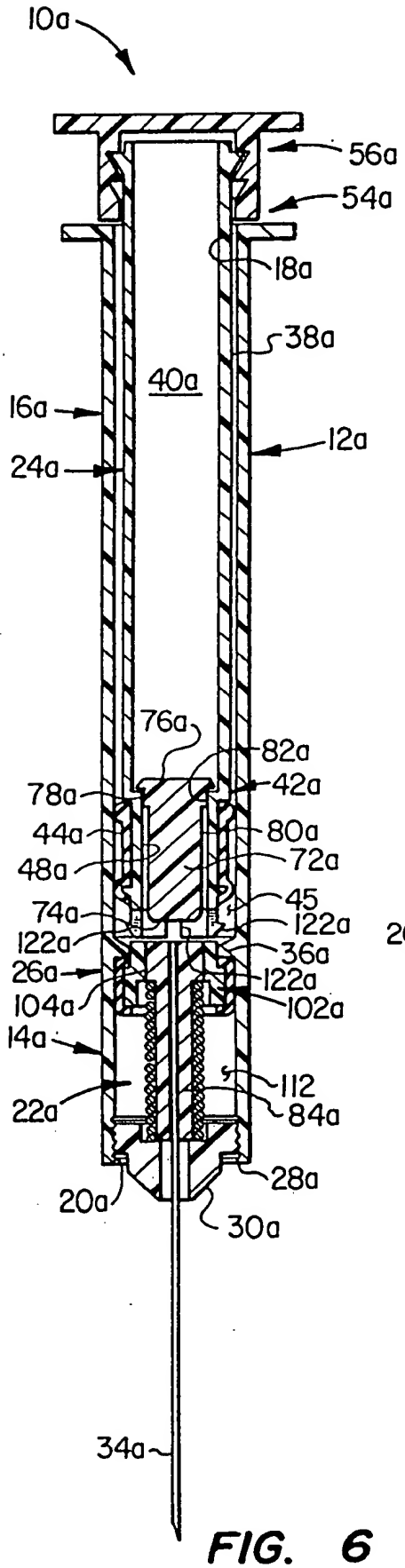


FIG. 6

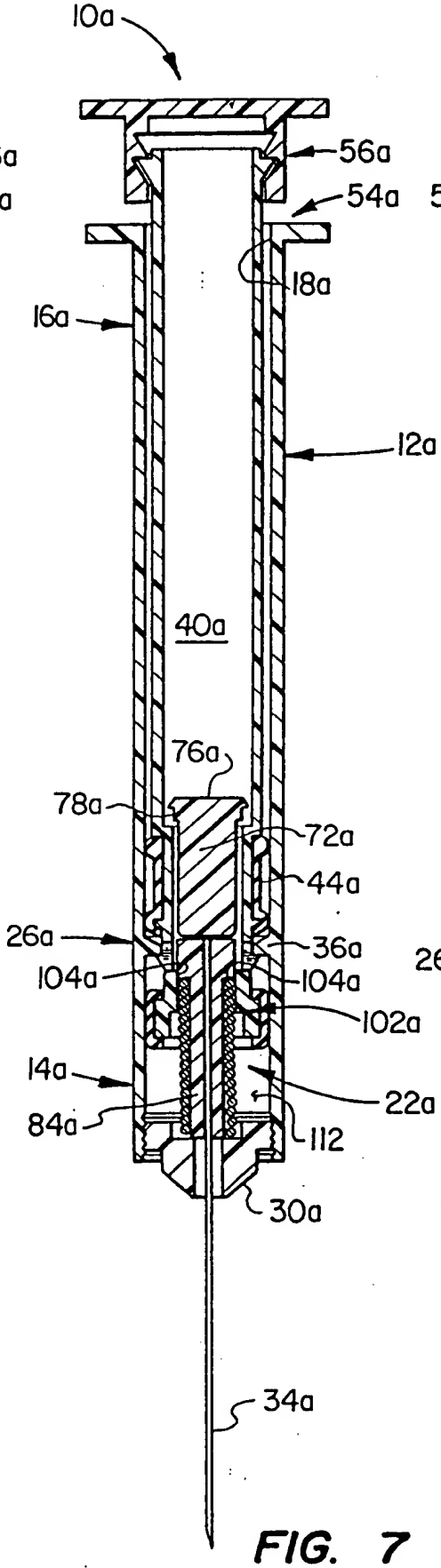


FIG. 7

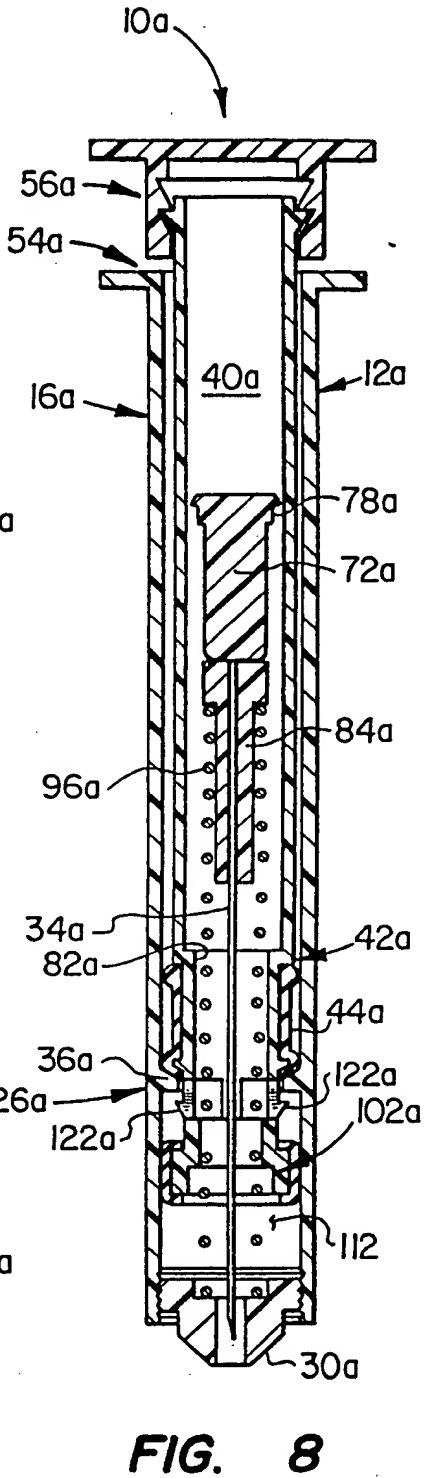


FIG. 8

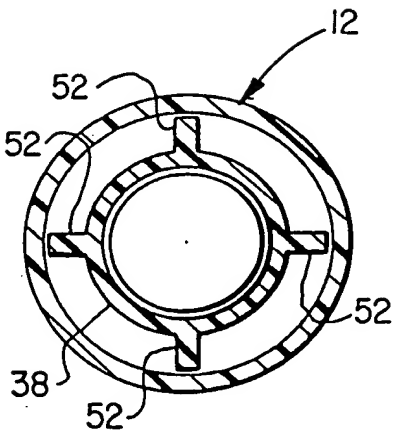
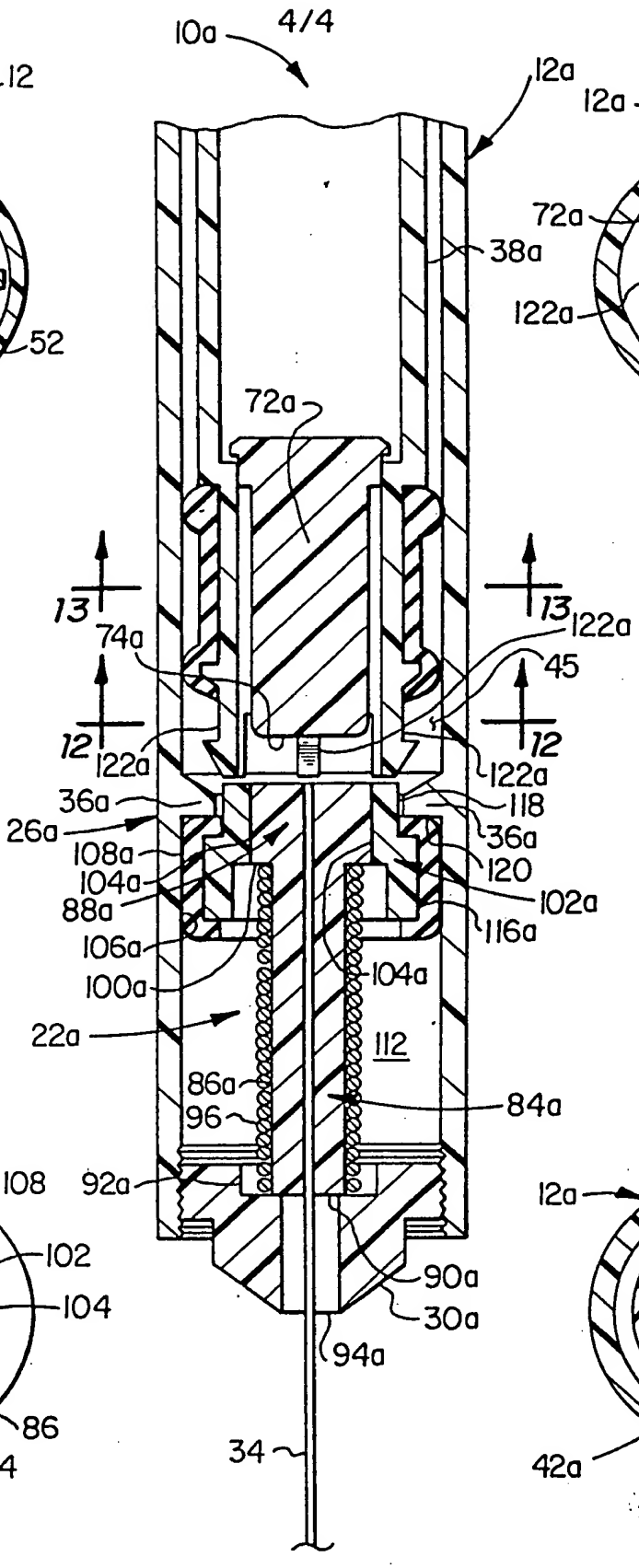


FIG. 10



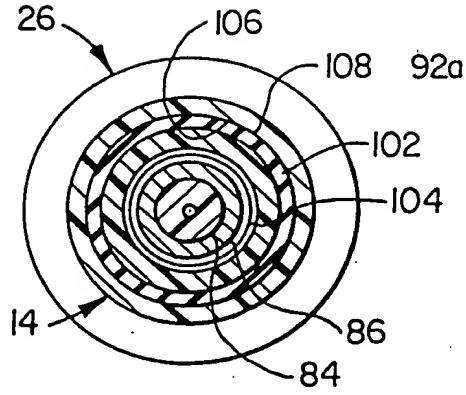


FIG. 11

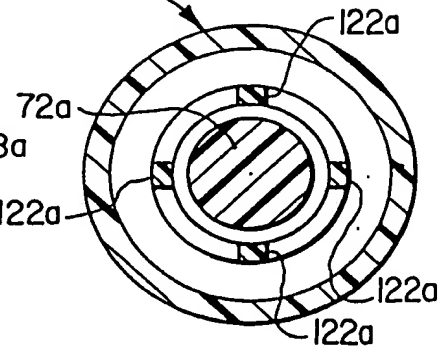


FIG. 12

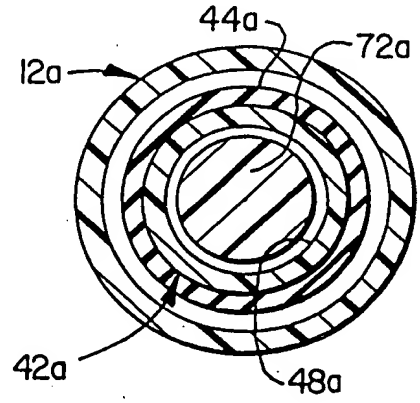


FIG. 13

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/10235

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M1500
US CL :604/110

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/187, 195, 198, 218, 220, 263

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,114,410, (CARALT BATLLE), 19 May 1992. See entire document.	1-32
A	US, A, 5,180,369, (DYSARZ), 19 January 1993. See entie document.	1-32
A	US, A, 5,211,629, (PRESSLY ET AL.), 18 May 1993. See entire document.	1-32
A	US, A, 5,201,710, (CASELLI), 13 April 1993. See entire document.	1-32

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 NOVEMBER 1994	JAN 31 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOHN D. YASKO, JR. Telephone No. (703) 308-2986

Form PCT/ISA/210 (second sheet)(July 1992)*